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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Docket No. 98P-0043: "Food Labeling: Nutrition Labeling of Dietary Supplements on a 'Per Day' Basis" – Proposed Rule

Dear Madam / Sir:

Whitehall-Robins Healthcare, a Division of American Home Products Corporation, is submitting these written comments and recommendations to Docket No. 98P-0043 on the Proposed Rule, "Food Labeling: Nutrition Labeling of Dietary Supplements on a 'Per Day' Basis," as published in the 64 *Federal Register* 1765 (January 12, 1999).

Whitehall-Robins Healthcare is providing comments, as requested by the Agency, on the following issues:

- Optional "per day" nutrient listing in addition to required "per day" serving listing;
- Format of label for "per day" basis in addition to "per serving" basis; and,
- Sample label of suggested format for dietary supplements that includes both "per day" and "per serving" basis.

Optional "Per Day" Nutrient Listing in addition to Required "Per Serving" Listing

Whitehall-Robins would like to convey our support for the Proposed Rule to allow the use of a "per day" listing on products that are recommended for consumption more than one time each day, in addition to the "per serving" listing currently permitted. We agree that allowing the use of the "per day" listing would provide important nutrition information to consumers who may use products multiple times each day, per the product label. Providing the total daily intake of a dietary ingredient would allow consumers to make educated decisions about their use of the product.

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Format of Labeling for “Per Day” Basis in addition to “Per Serving” Basis

We agree that it is critical to clearly label columns so as to minimize any confusion that consumers may have when reading a dietary supplement label. Since an optional “per unit” listing is also currently permitted in addition to “per serving,” we believe that the addition of a clearly labeled optional “per day” column that includes the amount and percent daily value would further help clarify nutrition information, rather than confuse consumers.

Sample Label of Suggested Format for Dietary Supplements that includes Both “Per Day” and “Per Serving” Basis

Finally, we agree with the proposal to add a sample label that includes a “per day” nutrient content listing to 21 CFR 101.36(e)(11)(viii). A sample label will provide clarification for dietary supplement manufacturers on the specific format and content requirements.

Whitehall-Robins Healthcare appreciates the opportunity to comment on the Proposed Rule, “Food Labeling: Nutrition Labeling of Dietary Supplements on a ‘Per Day’ Basis” and we have enclosed the requested two copies of our comments to the Docket. In summary, we fully support this Proposed Rule since it allows for communication of potentially important product information for consumers.

Sincerely yours,

WHITEHALL-ROBINS HEALTHCARE



Eleanor F. Barbo
Senior Director, Regulatory Affairs